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Atty Dkt. No.: MSSM-001
USSN: 10/760,151

REMARKS

In view of the following remarks, the Examiner is requested to withdraw the rejections and allow Claims 1-13, 15-19 and 43-47, the only claims pending and currently under examination in this application.

FORMAL MATTERS:

Claims 1 and 18 have been amended to now recite that the structure is **configured** for attachment to the prolapsing leaflet at the prolapsing segment and does not affect the mobility of the **opposing** leaflet. Support for this amendment is found throughout the specification, for example, at para [0039] and para [0043].

Claims 3, 4, 10 and 11 have been withdrawn.

Claims 14 and 20-42 have been previously canceled.

REJECTIONS UNDER §112, ¶1

Claims 1, 2, 5-9, 12, 13, 15-19 and 43-47 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement.

Specifically, the Office Action states that a physical structure made of matter for attachment to the prolapsing leaflet has to affect the mobility of the leaflet to some extent because it would inherently change the collective mass of the leaflet and physical structure (Office Action, P.2).

Claims 1 and 18 have been amended to specify that the structure does not affect the mobility of the **opposing** leaflet. As such, in view of the above amendments to Claims 1 and 18, the Applicant submits that this rejection may be withdrawn.

REJECTIONS UNDER §102

Claims 1, 2, 5, 7-9, 12, 16-19 and 43-47 have been rejected under 35 U.S.C. 102(b) as being anticipated by Dardik et al. (U.S. Patent No. 3,988,782).

As stated in the MPEP § 2103: "A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

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The present invention is drawn to systems and devices for repairing a regurgitant cardiac valve having two or more leaflets and a subvalvular structure wherein at least one leaflet has a prolapsing segment. An element of the instant claims is a structure configured for attachment to the prolapsing leaflet at the prolapsing segment that does not affect the mobility of the opposing leaflet. The structure further defines a coaptation surface against which an opposing leaflet coapts during systolic contraction of the heart whereby the coaptation between the leaflets is normalized and the coaptation surface is configured to extend freely beyond a free margin of the prolapsing segment when the structure is operatively implanted within the valve.

In contrast, Dardik et al. is drawn to a prosthesis made from a flexible, hardened segment of a mammalian umbilical cord. According to the disclosure, the prosthesis may be used as reinforcements and replacements for vessels, ducts, intestines and urinary bladders.

However, nowhere in the disclosure does the reference teach or suggest a device which is configured for attachment to the prolapsing leaflet at the prolapsing segment which does not affect the mobility of the opposing leaflet as in the present invention. As such, Dardik et al. fails to teach or suggest each and every element of the instant claims.

In view of the foregoing discussion, the Applicant respectfully requests withdrawal of this rejection.

Claims 1, 5-9, 12, 16-19 and 43-47 have been rejected under 35 U.S.C. 102(b) as being anticipated by Saxon (U.S. Patent No. 5,725,577).

As set forth above, an element of the instant claims is a structure configured for attachment to the prolapsing leaflet at the prolapsing segment which does not affect the mobility of the opposing leaflet.

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However, Saxon describes a prosthesis for repairing a soft tissue defect. According to Saxon's disclosure, the prosthesis comprises a first portion of a first material which does not incorporate into the host tissue and a second portion of a second material which does incorporate into the host tissue.

However, nowhere in the disclosure does the reference teach or suggest a device which is configured for attachment to the prolapsing leaflet at the prolapsing segment which does not affect the mobility of the opposing leaflet as in the present invention. As such, Saxon fails to teach or suggest each and every element of the instant claims.

In view of the foregoing discussion, the Applicant respectfully requests withdrawal of this rejection.

REJECTIONS UNDER §103(a)

Claims 13 and 15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Dardik et al. (U.S. Patent No. 3,988,782).

With respect to rejections made under 35 U.S.C. § 103, MPEP § 2142 states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). [emphasis added]

As discussed above, Dardik et al. fails to teach or suggest a device which is configured for attachment to the prolapsing leaflet at the prolapsing segment and does not affect the mobility of the

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opposing leaflet as in the present invention. As Claims 13 and 15 depend from Claim 1, these claims are patentable over the cited reference for at least the reasons discussed above.

In view of the foregoing discussion, the Applicant respectfully requests withdrawal of the rejection.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number MSSM-001.

Respectfully submitted,
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Date: 12-18-06

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